

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

TAKEDA GMBH, ASTRAZENECA
PHARMACEUTICALS LP, and
ASTRAZENECA UK LIMITED,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 1:15-cv-00093

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO STAY LITIGATION
PENDING RESOLUTION OF JURISDICTIONAL CHALLENGE TO
FIRST-FILED NEW JERSEY CASE OR RESOLUTION OF
FEDERAL CIRCUIT APPEALS IN SIMILAR CASES**

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I. INTRODUCTION

In their opening brief, Plaintiffs demonstrated that their motion to stay this action should be granted for several reasons. **First**, Mylan's jurisdictional challenge in the New Jersey Action does not foreclose application of the first-to-file rule. **Second**, Plaintiffs have not engaged in forum shopping by filing their principal case in New Jersey, where the majority of the defendants are domiciled. **Third**, the New Jersey Action has not stalled and fallen behind the present case as Mylan asserts. **Fourth**, a stay would conserve the Court's and the parties' resources by preventing two substantively identical actions from proceeding in two separate forums, as well as eliminating the risk of inconsistent pretrial rulings—especially where, as here, the New Jersey Action is just one of ten cases involving the same patents pending in New Jersey.

Mylan's response to these points, Dkt. 18, fails to distinguish the authority supporting Plaintiffs' request. Plaintiffs therefore respectfully request that a stay be granted either under the first-to-file rule or the Court's inherent authority.

II. ARGUMENT

As explained in detail in Plaintiffs' opening brief, Dkt. 14, the first-to-file rule and the Court's inherent discretion to manage its docket both provide a basis for a stay.

A. The Court Should Stay this Case Under the First-to-File Rule.

The prerequisites to the first-to-file rule are satisfied, and no exception to the rule applies.

1. Mylan's jurisdictional challenge in the New Jersey Action does not foreclose application of the first-to-file rule.

Plaintiffs cited in their opening brief many cases—in this jurisdiction and elsewhere—that applied the first-to-file rule in the face of jurisdictional and venue challenges brought in the first-filed forum. *See* Dkt. 14, at 6 n.4. In its opposition, Mylan does not address any of these cases in its opposition brief, much less attempt to distinguish them. Instead, Mylan relies heavily on *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed. Cir. 1993), *abrogated on other grounds*, *Wilton v. Seven Falls Co.*,

515 U.S. 277 (1995), which it argues necessarily forecloses the application of the first-to-file rule here.¹

That is not the case.

The *Genentech* court rejected the notion that a first-filed declaratory judgment action should give way to a later-filed suit, as such a rule would cause a “shift of relationship between litigants.” *Id.* at 937. Instead, the court ***expressly applied the first-to-file rule*** to find that plaintiff’s first-filed suit ought not to have been dismissed as to one of the defendants. *Id.* at 938-39. The court also noted that jurisdictional disputes in the first forum do not automatically foreclose application of the first-to-file rule, but should do so only when application of the rule “would make it unjust or inefficient to continue the first-filed action.” *Id.* at 938. Thus, the Federal Circuit described the “absence of jurisdiction over all necessary or desirable parties” in the first-filed forum as an exception to the first-to-file rule, *id.*, which, as this Court has frequently noted, should be addressed by the court hearing the ***first-filed case***, *see Pfizer, Inc. v. Mylan, Inc.*, 2009 WL 10270101, at *2-3, n.2 (N.D.W. Va. Nov. 20, 2009); *see also Salix Pharm., Ltd. v. Mylan Pharm. Inc.*, No. 1:14-cv-00152, Dkt. 47, at 7-8 (N.D.W. Va. Feb. 18, 2015). Thus, Mylan’s assertion that *Genentech* requires the Court to disregard the first-to-file rule is inconsistent with the holding in that case.²

Mylan’s attempt to analogize to *Novartis Pharmaceuticals Corp. v. Mylan Inc.*, No. 1:14-cv-00106, Dkt. 47 (N.D.W. Va. Jan. 27, 2015), in which this Court denied a motion to stay, is also unavailing. In *Novartis* this Court emphasized that the jurisdictional issue pending in the first-filed forum was “significantly complicated.” *Id.* at 5. Nine district courts—including three in the District of New

¹ Although the Federal Circuit noted in *Genentech* that the “absence of jurisdiction over all necessary or desirable parties” in the first-filed forum “***may***” constitute a reason not to apply the first-to-file rule, that statement was mere dictum. *Id.* at 938 (emphasis added). Personal jurisdiction was not disputed in either forum in that case, and therefore the Federal Circuit’s statement was irrelevant to its holding.

² *Orthmann v. Apple River Campground, Inc.*, 765 F.2d 119 (1985), sometimes cited for the proposition that the first-to-file rule should not apply when jurisdiction in the first forum is “vigorously” disputed, is similarly inapplicable. That case involved an appeal from a district court’s dismissal for lack of personal jurisdiction in the first forum—a motion to stay was never at issue in either court. *See id.* at 120-21. Unlike here, the district court in the first-filed forum had already determined that it lacked personal jurisdiction over the defendant.

Jersey—have now ruled on Mylan’s nearly identical motions to dismiss for lack of personal jurisdiction. All nine of those courts have exercised jurisdiction over Mylan. *See* Dkt. 14, at 7; *see also Boehringer Ingelheim Pharma GmbH & Co. KG v. Teva Pharm. USA, Inc.*, No. 3:14-cv-07811, Dkt. 76 (D.N.J. July 16, 2015). The jurisdictional issue in the New Jersey Action is now well settled.

Thus, this case should be stayed in favor of the first-filed action in New Jersey.

2. Plaintiffs have not engaged in forum shopping.

Many courts, including this Court, have consistently rejected arguments that filing a protective suit somehow constitutes “forum-shopping.” *See* Dkt. 14, at 8, 9; Dkt. 18, at 5-6. This Court has explained that the “peculiar enforcement requirements of the Hatch-Waxman Act . . . place incredible risks on patent holders who file . . . in a single jurisdiction.” *Mylan*, 2009 WL 10270101, at *2. Other courts have made the same observation. *See PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007) (finding that a protective suit does not show bad faith or improper forum shopping); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (same); *Pfizer Inc. v. Apotex Inc.*, 640 F. Supp. 2d 1006, 1010 (N.D. Ill. 2009) (rejecting argument that because plaintiff chose to file protective ANDA suit, “any effort to avoid litigating” that suit “evinces bad faith” by plaintiff). Mylan fails to address or distinguish any of this authority.

Moreover, Mylan’s assertion that Plaintiffs’ selected New Jersey as a forum for tactical reason, Dkt. 18, at 6, is unfounded. The defendants in the New Jersey actions are either domiciled in or have substantial connections to New Jersey. The vast majority of the ten groups of defendants Plaintiffs have sued in New Jersey have not challenged the appropriateness of that forum. Indeed, Mylan is the only defendant that has filed a motion to dismiss. Because Mylan’s jurisdictional challenge in New Jersey was foreseeable given its similar (and unsuccessful) challenges in other recent Hatch-Waxman cases, Plaintiffs brought suit against Mylan in this jurisdiction solely as a safety measure.

Thus, Plaintiffs have not engaged in forum shopping, and the first-to-file rule should apply.

3. The prerequisites to the first-to-file rule are satisfied.

Finally, as also shown in Plaintiffs’ opening brief, the prerequisites to the first-to-file rule are satisfied. Mylan’s arguments that (a) the New Jersey Action has “stalled” and is now behind the current case, and (b) the issues in each case are not identical, both fail.

a. This case has not advanced beyond the New Jersey Action so as to foreclose application of the first-to-file rule.

Mylan’s argument that this case has advanced ahead of the New Jersey Action, and that the first-to-file rule should therefore not apply, *see* Dkt. 18, at 5-6, is legally and factually incorrect.

As a legal matter, the first-to-file rule requires a court to determine, not whether the first-filed action remains procedurally ahead of the second-filed action at the time a motion to stay the second action is filed, but whether the first-filed action *was filed first*. *See Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012) (explaining that “the date of Merial’s contempt *motion* is irrelevant in determining which *action* was filed first—what matters is the initiation of suit”); *Peregrine Semiconductor Corp. v. RF Micro Devices, Inc.*, 2012 WL 2068728, at *9 (S.D. Cal. June 8, 2012) (“Defendants provide no authority for their contention that the first-to-file rule applies to an earlier filed motion to transfer. In discussing the first-to-file rule, the Ninth Circuit and the Federal Circuit have referred to the filing of complaints not the filing of motions to transfer. Therefore, this argument is unpersuasive.” (citations omitted)). The New Jersey Action was filed first. *See* Dkt. 14, at 5.

As a factual matter, Mylan’s premise—that this case has progressed to a more advanced stage compared to the New Jersey Action, which Mylan asserts is “at a standstill”—is also incorrect (and irrelevant). *See* Dkt. 18, at 5, 7. Eight of the ten defendants have answered the complaints filed in the District of New Jersey.³ The court set scheduling conferences in two of the cases for August 18 and September 24, respectively.⁴ In response to Plaintiffs’ letter concerning coordination or consolidation,

³ In addition to Mylan, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively, “Torrent”) have yet to file their answer. Torrent’s answer is due by September 1, 2015.

⁴ *See Takeda GmbH v. Apotex Corp.*, No. 3:15-cv-03379, Dkt. 14 (D.N.J. July 23, 2015); *Takeda GmbH v. Citron Pharma LLC*, No. 3:15-cv-03383, Dkt. 12 (D.N.J. July 22, 2015).

Judge Wolfson entered an order assigning all ten cases to Magistrate Judge Arpert for all pre-trial proceedings. *See Takeda GmbH v. Citron Pharma LLC*, No. 3:15-cv-03383, Dkt. 16 (D.N.J. July 28, 2015). Magistrate Judge Arpert later adjourned the scheduling conferences in favor of a coordinated status conference to be promptly scheduled as soon as the remaining defendant files its answer, which is expected to occur by September 1, 2015, at the latest.⁵

b. This Action and the New Jersey Action are sufficiently identical for purposes of the first-to-file rule.

The New Jersey Action and the present case are virtually identical in scope. In the New Jersey Action, Plaintiffs allege that Mylan infringes the claims of four valid patents. As such, the issues of infringement and validity raised in Mylan's counterclaims are already at issue in the New Jersey Action. Mylan's argument that the first-to-file rule should not apply here because it has filed counterclaims in this case and not in the New Jersey Action is therefore misplaced. Dkt. 18, at 7 (arguing that "the issues involved in this action are not identical" to those involved in the New Jersey Action).

Moreover, other defendants in the New Jersey actions have filed counterclaims asserting invalidity and non-infringement of the same patents asserted against Mylan. Thus, those issues will be litigated in the context of the coordinated or consolidated actions in New Jersey. The only reason that counterclaims of invalidity and noninfringement are at issue in this case and not explicitly in the Mylan-specific New Jersey Action is because Mylan chose to answer the complaint in this case and not in the New Jersey Action. Mylan cannot credibly argue that it will not file identical counterclaims in the New Jersey Action in the event its motion to dismiss is denied.

At any rate, the absence of certain counterclaims in the first-filed case is irrelevant to whether the first-to-file rule applies. *See GlycoBioSciences, Inc. v. Nycomed US, Inc.*, 2012 WL 540928, at *2 (E.D.N.Y. Feb. 15, 2012) (noting that the first-to-file rule "does not require *identical* complaints but rather 'substantial overlap' of the parties and claims in both actions" (citation omitted)); *Your Preferred*

⁵ See Clerk's Note, *Takeda GmbH v. Apotex Corp.*, No. 3:15-cv-03379 (D.N.J. July 29, 2015); Clerk's Note, *Takeda GmbH v. Citron Pharma LLC*, No. 3:15-cv-03383 (D.N.J. July 29, 2015).

Printer, LLC v. United Wholesale, LLC, 2012 WL 3016771, at *4 (E.D. La. July 23, 2012) (“[T]hat each suit raises claims not present in the other does not counsel against adhering to the first-to-file doctrine.”). Thus, Mylan’s counterclaims cannot form the basis for avoiding the first-to-file rule.

B. The Court Should Stay this Case Pursuant to its Inherent Powers.

Alternatively, the Court should exercise its inherent powers to stay the case in order to conserve judicial resources and avoid undue prejudice to Plaintiffs.

1. The interests of judicial economy favor a stay.

Mylan’s conclusory assertion that a stay would not result in judicial economy is incorrect. *See* Dkt. 18, at 8. For the reasons stated above, this action has not “progressed significantly further than the New Jersey action,” as Mylan alleges. *See id.* Thus, judicial resources would not be wasted by waiting for the first-filed case to proceed, in contrast to other cases in which this Court has denied motions to stay. *See Novartis*, No. 1:14-cv-00106, Dkt. 47 (discovery had begun in second-filed suit); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm., Inc.*, No. 1:15-cv-00010, Dkt. 37 (N.D.W. Va. Mar. 27, 2015) (same).

And, unlike in *Novartis*, where the first-filed case could not “be consolidated with any of the other” cases in the first-filed forum involving the same pharmaceutical product, which had “already progressed past trial,” *Novartis*, No. 1:14-cv-00106, Dkt. 47, at 13, the cases pending in the District of New Jersey have already been assigned to a single magistrate judge for coordinated pre-trial proceedings. *See Citron*, No. 3:15-cv-03383, Dkt. 16. Thus, if this case were not stayed, Plaintiffs would have to litigate this action in parallel to an action in New Jersey involving identical issues.

2. The prejudice to Plaintiffs if this Action is not stayed outweighs any potential prejudice to Mylan if the Action is stayed.

Mylan’s assertion that Plaintiffs would not suffer hardship if this Action were not stayed is also incorrect. *See* Dkt. 18, at 9-10. As explained in Plaintiffs’ opening brief, Plaintiffs would be forced to litigate against Mylan in this district, while maintaining actions in New Jersey against nine other defendants involving the same patents. *See* Dkt. 14, at 13-14. Plaintiffs would face duplicative discovery and motions practice. Their employees would be subjected to multiple depositions on the very same

issues. And, the parallel proceedings would open the possibility for inconsistent results. *See Eli Lilly & Co. v. Mylan Pharm., Inc.*, -- F. Supp. 3d --, 2015 WL 1125032, at *7 (S.D. Ind. Mar. 12, 2015) (denying Mylan's motion to dismiss and recognizing that "resolving this case in one forum would promote both judicial efficiency and also avoid the possibility of inconsistent results").

Moreover, Mylan's assertion that it would be prejudiced if this Action were stayed is also incorrect. *See* Dkt. 18, at 10-11. Unlike in *Novartis*, Mylan is not "faced with the possibility of" "a long wait" for its jurisdictional challenge to be resolved. *Novartis*, No. 1:14-cv-00106, Dkt. 47, at 14. Mylan's motion to dismiss is now fully briefed and, as explained above and in Plaintiffs' opening brief, post-*Daimler* jurisdictional case law is now well developed and supports a finding of jurisdiction in New Jersey. At any rate, Plaintiffs request only that this case be stayed pending *the earlier of* the New Jersey court's jurisdictional decision *or* the Federal Circuit's decisions on Mylan's appeals. Thus, it is unlikely "that a delay of limited duration to resolve a jurisdictional motion" filed by Mylan itself would cause Mylan "*undue* prejudice." *Apotex*, 640 F. Supp. 2d at 1008-11 (granting stay of second-filed ANDA case on similar facts). To the extent the Mylan would suffer any prejudice, it is far outweighed by the prejudice faced by Plaintiffs if this case is *not* stayed.

III. CONCLUSION

For the reasons set forth above and in their opening brief, Dkt. 14, Plaintiffs respectfully request that the Court stay this case pending the earlier of the resolution of (1) Mylan's motion to dismiss in the New Jersey Action, or (2) Mylan's jurisdictional Federal Circuit appeals in similar cases.

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CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2015, the foregoing PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO STAY LITIGATION PENDING RESOLUTION OF JURISDICTIONAL CHALLENGE TO FIRST-FILED NEW JERSEY CASE OR RESOLUTION OF FEDERAL CIRCUIT APPEALS IN SIMILAR CASES was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification to the following registered attorneys of record that the document has been filed and is available for viewing and downloading:

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